IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC. Plaintiff and Counterclaim Defendant, v. RANBAXY, AND RANBAXY LABORATORIES LIMITED Defendants and Counterclaim Plaintiffs.	)	C.A. No. 07-229 (GMS)

MERCK'S BRIEF IN SUPPORT OF ITS MOTION FOR LEAVE TO FILE ITS FIRST SUPPLEMENTAL COMPLAINT

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Dated: January 11, 2008

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

OTHER AUTHORITIES

INTRODUCTION

Pursuant to Rule 15(d), Fed. R. Civ. P., Plaintiff Merck & Co., Inc. ("Merck") seeks to file its Supplemental Complaint to update the pleadings concerning events that occurred after the filing of the original Complaint: Ranbaxy's filing of two additional ANDAs, for products with the same active ingredients as the original ANDA already in this lawsuit, and the issuance of a Certificate of Correction ("COC") for the patent-in-suit, U.S. Patent No. 5,147,868 ("the '868 patent"). Merck's Supplemental Complaint will not require additional discovery and will not affect the Court's schedule in this case. Merck's Supplemental Complaint will promote the complete and just adjudication of the disputes between the parties, is not futile, is timely filed and in good faith, and will not prejudice Ranbaxy in any way.

NATURE AND STAGE OF PROCEEDINGS

On April 30, 2007, Merck filed its original Complaint in this case for infringement of the '868 patent. The '868 patent relates to a novel class of compounds, including the compound cilastatin. Cilastatin is one of the active ingredients, along with imipenem, in Primaxin®, a potent antibiotic product sold by Merck, which is used primarily in hospitals to treat difficult infections. The Complaint in this case related to Ranbaxy's filing of an Abbreviated New Drug Application ("ANDA I") with the FDA prior to the filing of the original Complaint on April 30, 2007, to market products containing cilastatin and imipenem ("Product I"). On June 21, 2007, Ranbaxy filed its Answer and Counterclaims, asserting various defenses, including multiple invalidity defenses with respect to the '868 patent.

On September 19, 2007, the Court held a scheduling conference with the parties. The Court scheduled eight months for fact discovery, ending May 30, 2008, as the Court concluded, based on the parties' descriptions of the issues in the case, that this was a normal patent case. The Court set opening and rebuttal expert reports for March 28, 2008 and April 25,

2008, respectively. Trial is scheduled for one week starting September 15, 2008. The Court decided not to schedule summary judgment proceedings.

Claim construction briefing has been completed in this case and the *Markman* hearing is set for February 7, 2008. The parties are currently conducting document review and production, and have not yet scheduled depositions.

The date for amending the pleadings or adding new parties was originally scheduled for January 4, 2008. Upon agreement of the parties, the Court extended the deadline to January 11, 2008. On January 8, 2008, Merck provided Ranbaxy with a copy of its proposed Supplemental Complaint, pursuant to Local Rule 7.1.1. Ranbaxy stated that it opposed the filing of Merck's Supplemental Complaint on the grounds that each of the new counts relate to the COC for the '868 patent and that the "Certificate of Correction is not effective in this case." (Exhibit A, Boland letter to Bonifield, 1/9/08).

STATEMENT OF FACTS

A. Ranbaxy's Additional ANDAs

Subsequent to the filing of this lawsuit, in summer, 2007, Ranbaxy filed two additional ANDAs (respectively, "ANDA II" and "ANDA III") for different proposed injectable products comprising imipenem and cilastatin sodium (respectively "Product II" and "Product III"). Products II and III contain imipenem and cilastatin in the same dosages as Product I for the same use as injections. ANDA II and ANDA III were prepared based on different packaging of the proposed products.

Discovery has been proceeding on all three ANDAs and Products I, II, and III. Ranbaxy has produced at least portions of ANDA II and ANDA III to Merck. Products II and III have the same two active ingredients as the first product already at issue, including the cilastatin compound claimed in the '868 patent. Thus, the issues relating to infringement should be the

same for Products I, II, and III. The inclusion of Products II and III in this lawsuit should not require any additional discovery beyond routine updates of documents exchanged with the FDA.

B. The '868 Patent Certificate Of Correction

Also subsequent to the filing of this lawsuit, the Patent Office issued a Certificate of Correction ("COC") on the '868 patent on November 6, 2007. The COC relates to a minor error on the face of the '868 patent and in the first paragraph of the specification. Specifically, those portions of the '868 patent did not recite one of the parent applications in the chain of Related U.S. Application Data. Ranbaxy contends that because of this error, the '868 patent is not entitled to the priority date of that parent application and that the patent was therefore invalid.

It is Merck's primary position that the error on the '868 patent has no effect on the priority date or validity of the '868 patent. However, because the error is one that is easily corrected in the PTO by the issuance of a COC, and because the patent with the COC would be applicable to any infringing activity that occurs after the issuance of the COC, Merck sought a COC from the Patent Office. Thus, to the extent the error in the originally issued patent has any legal effect, any issues relating to that are eliminated with respect to any infringing activity of Ranbaxy's that occurs in the future. *Southwest Software, Inc. v. Harlequin, Inc.*, 226 F.3d 1280, 1294 (Fed. Cir. 2000) ("[I]f claim 1 is found to have been invalid without the Program Printout Appendix, ***the invalidity ceased*** on April 1, 1997, when the PTO ***issued the certificate of correction***.")[1]

Consequently, on May 17, 2007, Merck requested a COC for the '868 patent to insert references to the application number omitted from the face of the '868 patent and the first

[1] Unless otherwise indicated all emphasis in this brief has been added.

paragraph. On November 6, 2007, the PTO issued a COC for the '868 patent inserting the requested references.

C. Merck's Proposed Supplemental Complaint

Merck's Supplemental Complaint would add four new counts, Counts III, IV, V and VI. Count III seeks a declaratory judgment that products covered by ANDA I will infringe the '868 patent with the COC. Counts IV and V seek declaratory judgments that the products covered by Ranbaxy's two new ANDAs, ANDA II and ANDA III, will infringe the '868 patent. Count VI seeks a declaratory judgment that the '868 patent with the COC is not invalid.

Pursuant to Delaware Local Rule 15.1, Merck has attached the Supplemental Complaint to this motion. Also attached is a red-lined version showing the differences between the Supplemental Complaint and the originally filed Complaint.

ARGUMENT

Merck should be granted leave to supplement its original Complaint pursuant to Rule 15(d) to add Counts III, IV, V, and VI.

I. MERCK'S MOTION SHOULD BE GRANTED GIVEN THE LIBERAL STANDARD FOR SUPPLEMENTAL PLEADINGS OF FEDERAL RULE OF CIVIL PROCEDURE 15(d)

Rule 15(d) provides, in relevant part, that "[o]n motion and reasonable notice, the court may, on just terms, permit a party to serve a supplemental pleading setting out any transaction, occurrence, or event that happened after the date of the pleading to be supplemented." Fed. R. Civ. P. 15(d). Merck's Supplemental Complaint sets out events that occurred after Merck filed its original Complaint on April 30, 2007, including the issuance of the COC and the filing of Ranbaxy's two new ANDAs for Product II and Product III. Thus, Merck's proposed pleading is a supplemental complaint governed by Rule 15(d), rather than an

amended complaint governed by Rule 15(a). *See, e.g., Abbott Diabetes Care, Inc. v. DexCom, Inc.*, No. 05-590-GMS, 2006 WL 2375035, at *4 (D. Del. August 16, 2006).

The standard for granting a motion under Rule 15(d) is "essentially the same" as that under 15(a), which provides that "[t]he court should freely give leave when justice so requires." *Marvel v. Snyder*, No. 99-442-GMS, 2001 WL 830309, at *6 n.4 (D. Del. July 24, 2001) (Sleet, J.). Leave to supplement a pleading "should be granted if it will promote the just disposition of the case, will not cause undue prejudice or delay and will not prejudice the rights of any parties." *Medeva Pharma Ltd. v. Am. Home Prods. Corp.*, 201 F.R.D. 103, 104 (D. Del. 2001); *see also, The Proctor & Gamble Co. v. McNeil-PPC, Inc.*, No. 98-361-GMS, 1998 WL 1745118, at *1 (D. Del. Dec. 7, 1998). In addition, a court may deny the requested leave if the amendment or supplement would be futile. *Foman v. Davis*, 371 U.S. 178, 182 (1962). In the absence of futility or undue delay or prejudice, denial of the requested leave "is not an exercise of discretion; it is merely abuse of that discretion and inconsistent with the spirit of the Federal Rules." *Foman*, 371 U.S. at 182; *see also, Alvin v. Suzuki*, 227 F.3d 107, 121 (3d Cir. 2000).

As set forth in the following sections, Merck's Supplemental Complaint will promote the just disposition of this case, would not be futile, is timely and in good faith, and will not prejudice Ranbaxy.

II. MERCK'S SUPPLEMENTAL COMPLAINT WILL PROMOTE THE COMPLETE AND JUST DISPOSITION OF THE DISPUTE BETWEEN THE PARTIES

Under Rule 15(d), a party should be granted leave to supplement the pleadings "to promote ***as complete an adjudication of the dispute between the parties as possible*** by allowing the addition of claims which arise after the initial pleadings are filed." *Coca-Cola Bottling Co. of Elizabethtown, Inc. v. Coca-Cola Co.*, 668 F. Supp. 906, 922 (D. Del. 1987), *vacated in part on other grounds*, 988 F.2d 386, 391 (3d Cir. 1993) (quoting *William Inglis & Sons Baking Co. v.*

ITT Con'l Baking Co., 668 F.2d 1014, 1057 (9th Cir. 1981)). Merck's Supplemental Complaint promotes the complete and just disposition of the dispute at issue in this case for two reasons.

First, Counts IV and V of the Supplemental Complaint seek declaratory judgments of infringement on Ranbaxy's proposed Product II and Product III, both of which contain the same cilastatin compound as the product already at issue in this case. The parties' dispute centers on whether Ranbaxy can sell certain cilastatin-containing products prior to the expiration of Merck's '868 patent. Consequently, a complete adjudication of the dispute between the parties in this case would require resolution of the infringement issues with respect to these two new products on which Ranbaxy filed ANDAs after the date of the original Complaint.

Second, the Supplemental Complaint requests a declaratory judgment regarding any infringing activities that occur after the issuance of the COC. Specifically, Counts III, IV, V and VI seek a declaration that sales of products containing cilastatin and imipenem in the future will infringe the '868 patent with the COC. If Ranbaxy ever attempts to launch its products, Ranbaxy's sales activity will necessarily occur after the COC was issued and will therefore be an infringement of the patent ***with the COC***. Thus, a central issue in the parties' dispute is whether the patent ***with the COC*** would be infringed by future sales. Keeping that issue out of this case will result in this case failing to completely adjudicate the dispute between the parties.

Indeed, if those counts are not added to the case, Merck could file an additional lawsuit in the future to adjudicate whether Ranbaxy's products infringe the patent with the COC, in particular with respect to the new causes of action that would arise when Ranbaxy launched any cilastatin-containing products. As a practical matter, it makes more sense to litigate that issue as a part of this lawsuit according to the schedule already adopted by the Court.

III. MERCK'S SUPPLEMENTAL COMPLAINT IS NOT FUTILE

Ranbaxy contends that Merck's Supplemental Complaint is futile because the COC for the '868 patent "is not effective in this case." (Exhibit A, Boland letter to Bonifield, 1/9/08). As shown below, however, the COC is effective with respect to any acts of infringement occurring after the issuance of the COC, including those activities referenced in Counts III, IV, V, and VI of the Supplemental Complaint, which all relate to activities that will occur in the future, after the COC issued.

A. Under 35 U.S.C. 255, The COC For The '868 Patent Is Effective With Respect To Count III, IV And V

Under 35 U.S.C. 255, a patent "together with the certificate [of correction] shall have the same effect and operation in law on the trial of actions for ***causes thereafter arising.***" The Federal Circuit held in *Southwest Software, Inc. v. Harlequin, Inc.,* that for any cause of action arising after the COC issued, the patent with the COC would govern. 226 F.3d at 1295 ("[F]or causes arising after the PTO issues a certificate of correction, the certificate of correction is to be treated as part of the original patent-i.e., as if the certificate had been issued along with the original patent."). New Counts III, IV, and V pertain to Ranbaxy's anticipated launch of its ANDA products. There can be no dispute that if Ranbaxy actually launches a cilastatin-containing product, that activity in the future will create multiple new causes of action arising well after the issuance of the COC.

Under Federal Circuit law, "each act of patent infringement gives rise to a ***separate cause of action***." *Hazelquist v. Goochie Moochie Tackle Co., Inc*., 437 F.3d 1178, 1180 (Fed. Cir. 2006). In *Hazelquist*, the issue involved whether new causes of action arose for continuing patent infringement after a bankruptcy discharge date. As the Federal Circuit explained, where there are a series of infringing activities, "each of those infringing activities

gives rise to a cause of action ***that dates from the moment of infringement.***" *Id.* at 1181. Indeed, the Federal Circuit noted that the later infringing acts give rise to "multiple causes of action, which arose after the bankruptcy discharge." *Id.*

Thus, under *Hazelquist*, there can be no dispute that Ranbaxy's future sales will be new post-COC causes of action. And under *Southwest Software*, those post-COC causes of action will be governed by the '868 patent with the COC. 226 F.3d at 1297 ("[W]e point out that, ***for any cause of action arising after*** April 1, 1997, ***the date the certificate of correction issued***, the certificate will be treated as part of the original patent.").

Under the Declaratory Judgment Act, Merck can seek resolution with respect to those post-COC causes of action in a declaratory judgment action. 28 U.S.C. § 2201. Counts III, IV, and V seek a declaratory judgment that Ranbaxy's manufacture and sale of its ANDA products in the future will infringe the '868 patent – an issue that squarely involves the '868 patent with the COC. The COC is therefore effective for Counts III, IV, and V, and Merck should be permitted to add those counts in its Supplemental Complaint.

B. Ranbaxy's Contention That The COC Is Not Effective In This Case Has No Merit

Ranbaxy contends that the COC is not effective in this case, citing this Court's decision in *ISCO Int'l, Inc. v. Conductus, Inc.*, which denied leave to file an amended complaint to add a reference to a COC. No. 01-487-GMS, 2002 U.S. Dist. LEXIS 21706 (D. Del. Nov. 8, 2002). In *ISCO*, the Court ruled that the COC was not effective for the purpose of the pending litigation. *Id.* at *6-7. The Court cited the Federal Circuit's ruling in *Southwest Software*, and noted that if the Court granted the plaintiff's request that the COC should apply to the lawsuit, "*Southwest* would be stripped of all meaning." *Id.* Ranbaxy apparently takes the position that a COC is not effective in a patent infringement suit that was filed before the date that the COC

issued, even for causes of action that arose after that date. *ISCO* did not adopt such a rule, and Ranbaxy's position contradicts controlling Federal Circuit law.

In *ISCO*, this Court did not address, and, as far as counsel is aware, the plaintiff/patent owner did not present, the issue of whether a COC issued after a lawsuit is filed is effective for causes of action that arise after the COC issued, even if the COC were ineffective for pre-COC infringing activities. It is apparent that the *ISCO* plaintiff, at the very least, argued that the COC was effective for infringing activities that occurred ***before*** the COC was issued. Indeed, the *ISCO* Plaintiff sought to amend the complaint at least in part in response to the defendant's motion for summary judgment relating to pre-COC causes of action:

> [T]he plaintiff and the defendants have submitted…numerous motions for summary judgment. These include Conductus' Motion for Summary Judgment of ***Invalidity of All Asserted Claims for Causes of Action Existing Prior to the Date of a Certificate of Correction*** and of Invalidity of Claim 13 ("the Conductus motion") (D.I. 205). The plaintiff has filed an answering brief in opposition to the Conductus motion, and conditionally moves for leave to file an amended complaint. The plaintiff's motion for leave to amend is conditional on the court's granting the Conductus motion for summary judgment. ***Should the court deny the Conductus motion, ISCO will withdraw its conditional motion for leave to amend.***

ISCO, 2002 U.S. Dist. LEXIS, at *2. Whatever the plaintiff's strategy in *ISCO*, it appears that the plaintiff did not present the issue of whether a COC would apply to infringing activity that occurs after the issuance of the COC, even if it did not apply to accused infringement occurring prior to the issuance of the COC.

Nor was that issue addressed in the cases cited in *ISCO*, including *Rambus, Inc. v. Infineon Techs AG*, 155 F. Supp. 2d 668, 677 at n.6 (E.D. Va. 2001); *Elec. Planroom v. McGraw-Hill Cos., & Estate of Devon Shire*, 135 F. Supp. 2d 805, 827 (E.D. Mich. 2001); and *Adrain v. Hypertech, Inc.*, 2001 WL 740542, at *3 (D. Utah 2001). In both *Rambus* and *Elec.*

Planroom, the effectiveness of a COC was not at issue in the case. In *Adrain*, as in *ISCO*, the patentee took the approach that the COC was effective retroactively, including for causes of action that arose before the certificate issued.

In *Southwest Software*, all of the infringing acts occurred prior to the issuance of the COC. Thus, in *Southwest*, the parties did not present the issue of the applicability of the COC for post-COC activities in that case. However, the Federal Circuit's statements and reasoning make it clear that the date of the cause of action determines whether a COC is effective, not the date of the lawsuit. The court expressly stated that the COC at issue in *Southwest Software* would be effective if any additional infringement occurred in the future. As the court explained, "we point out that, ***for any cause of action arising after*** April 1, 1997, ***the date the certificate of correction issued***, the certificate will be treated as part of the original patent." *Southwest Software*, 226 F.3d at 1297.

Indeed, the logic of the Federal Circuit's decision is consistent with the view that the relevant date is the date of the infringing activities, not the date of the lawsuit. The Federal Circuit held that the logic of the statute governing COCs requires focusing on the date of the infringing activities. Specifically, the court wanted to avoid "an illogical and unworkable result…where the claim is invalid on its face without the certificate of correction…[and] the patent holder, once the certificate of correction has issued…sue[s] an alleged infringer for activities that occurred before the issuance of the certificate of correction." *Id.* at 1295-96.

In *Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C.*, No. CV-00-2430, 2006 WL 4448613 (N.D. Ala. Jan. 10, 2006), *vacated on other grounds*, 482 F.3d. 1347 (Fed. Cir. 2007), the court closely analyzed and relied on the language quoted above in *Southwest Software*. The *Central Admixture* court pointed out that "the only

interpretation that avoids the result decried by the Federal Circuit is the interpretation that a COC applies only to causes of action arising after the issuance of the COC, regardless of when the lawsuit seeking to recover on those causes of action is filed." *Id.* at *59. Accordingly, the court in *Central Admixture* held that "a COC applies to *causes of action* arising after the COC's issuance, even if the lawsuit is filed prior to the COC's issuance." *Id.* (emphasis in original).

Similarly, in *Alltrade Tools, LLC., v. Olympia Group, Inc.,* No. 03-0458, 2003 U.S. Dist. LEXIS 26248, at *10 (C.D. Cal. Oct. 8, 2003), the district court allowed the patentee to amend pleadings to add a counterclaim requesting "prospective relief for patent infringement from July 2, 2003, the date of the Certificate of Correction." *See also Nat'l Prods., Inc. v. Palmetto West Trading Co., LLC*, No. C05-345JLR, 2006 WL 1207895 (W.D. Wash. May 4, 2006) (suggesting parties could request to amend their infringement and invalidity allegations based on a recently issued COC).

Consequently, Ranbaxy's argument is based on a misapplication of *ISCO* and is meritless.

C. Count VI of the Supplemental Complaint Is Not Futile

Moreover, independent of Ranbaxy's argument regarding the COC, Count VI is not futile. It seeks a declaratory judgment relating to Ranbaxy's contention that the patent with the COC is invalid. That issue would be raised in a future lawsuit governing future acts of infringement by Ranbaxy.

Ranbaxy has expressly stated to Merck that it believes the '868 patent is invalid by reason of the error that was corrected by the COC, even after the COC was issued. And Ranbaxy has threatened to launch its products and sell them in a time period where the patent with the COC will be in force. Consequently, the dispute over the alleged invalidity of the '868 patent raises the proper basis for declaratory relief. *Adenta GmbH v. OrthoArm, Inc.*, 501 F.3d

1364, 1369 (Fed. Cir. 2007) (declaratory judgment proper where "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment") (quoting *Medimmune, Inc. v. Genentech, Inc.*, ___ U.S. ____, 127 S. Ct. 764, 771 (2007)).

In particular, the dispute underlying the declaratory judgment action in Count VI is the alleged invalidity of the '868 patent ***with the COC***. As discussed above, Ranbaxy's future infringing sales will create multiple future causes of action. *Hazelquist*, 437 F.3d at 1180 ("[E]ach act of patent infringement gives rise to a ***separate cause of action***."). The Federal Circuit has made clear that, with respect to future causes of action, it is the validity of the patent with the COC that governs. *Southwest Software*, 226 F.3d at 1297 ("[I]f claim 1 is found to have been invalid without the Program Printout Appendix, ***the invalidity ceased*** on April 1, 1997, when the PTO ***issued the certificate of correction***.").

The declaratory judgment action in Count VI relates to the future causes of action that will arise when Ranbaxy launches its products. Thus, under *Southwest Software*, the COC for the '868 patent is effective for Count VI. Count VI is therefore not futile and Merck should be allowed to supplement its complaint with Count VI.

IV. MERCK'S SUPPLEMENTAL COMPLAINT IS TIMELY, IN GOOD FAITH, AND WILL NOT PREJUDICE RANBAXY

A party should be allowed to supplement the pleadings and "test its claim on the merits," where there is no undue delay, bad faith, or prejudice to the rights of the other party. *Medeva Pharma Ltd.*, 201 F.R.D. at 104. Although Ranbaxy objected to Merck's Supplemental Complaint, it did not dispute that the Supplemental Complaint is timely, in good faith, and will not prejudice Ranbaxy.

Indeed, there is no undue delay here because Merck brings this motion on the date set by the Court's Order of January 9, 2007. Moreover, Merck's Supplemental Complaint is submitted in good faith and will not prejudice Ranbaxy in any way. Document production is still ongoing, the parties have not begun depositions, and opening expert reports are not due until March 28, 2008. Indeed, Merck's Supplemental Complaint furthers judicial economy by incorporating the COC and additional ANDAs into the case now, rather than waiting until Ranbaxy launches its first products.

CONCLUSION

For the reasons stated above, Merck requests that the Court grant Merck leave to file its First Supplemental Complaint.

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Dated: January 11, 2008
1382073

CERTIFICATE OF SERVICE

I hereby certify that on January 11, 2008, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

Frederick L. Cottrell , III, Esquire
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Kelly E. Farnan, Esquire
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Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on January 11, 2008 upon the following individuals in the manner indicated:

BY EMAIL AND HAND DELIVERY

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January 9, 2008

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Re: Merck & Co., Inc. v. Ranbaxy Inc. et al., No. 07-229 (GMS)
Our Ref.: L10594

Dear Greg:

Thank you for your letter of January 8, 2008 enclosing Merck's proposed amended complaint. Ranbaxy will oppose any motion to amend. Each of the proposed new counts appears to relate to the "corrected" patent. The law is clear that a Certificate of Correction is not effective in this case. *See, e.g.*, ISCO INTERNATIONAL, INC. v. CONDUCTUS, INC., 2002 U.S. Dist. LEXIS 21706 (D. Del. 2002)(Sleet, J.). For at least this reason, the proposed amendment would be futile.

Very truly yours,

Mark Boland

Cc: Counsel of record